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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,199

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Itzhak Kronzon

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,199

Applicant(s)

KRONZON, ITZHAK

Examiner

Christopher A. Flory

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/15/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 117 in Figure 3c. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 5, the phrase "via a plurality of leads so that the selected ones of the are energized to supply cardioversion current" is unclear as to whether the electrodes or the power source is supplying the cardioversion current.

5. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "condom material" in claim 18 is indefinite because the specification does not clearly redefine the term and it is unclear whether Applicant intends the term to convey merely a thin, tightly fitting covering; a flexible sheath of a specific material, e.g. silicone or latex; a removable protective barrier; or any number of other meanings that might be construed by the term "condom."

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-10 and 12-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Friedman (US Patent Publication 2003/0097167, hereinafter referred to as Friedman'167).

Regarding claims 1-5, 10, 14 and 19, Friedman'167 discloses a medical apparatus used to treat cardiac arrhythmia comprising a flexible probe for accessing a patient's esophagus via the mouth with a proximal end which remains outside the patient and a distal end within the esophagus (TITLE; ABSTRACT; paragraphs [7], [10] and [32]); an echocardiography transducer coupled to the distal end at a predetermined location within the esophagus relative to the heart to perform transesophageal echocardiography (Fig. 1 TEE probe 3; paragraphs [6], [10] and [32]); and a plurality of electrodes spaced along a longitudinal axis of the probe (Fig. 2, electrodes 26; Fig. 3, leads 1-8) each coupled to a wire lead extending along the probe to a power source (paragraphs [9], [28] and [29]) for delivering a cardioversion or defibrillation current via the esophagus (paragraphs [15]-[17] and [36]-[38]).

Regarding claims 7 and 16-18, and further regarding claim 14, Friedman'167 discloses the electrodes mounted on or within a flexible sheath which is sized to be received over a distal portion of the probe and fixed thereon at a predetermined location relative to the echocardiography transducer (paragraphs [6], [7], [10]-[12] and [32]), the sheath being made of a flexible condom material (paragraph [32] discloses a sheath made of silicone).

Regarding claims 6 and 9, and further regarding claim 14, Friedman'167 discloses that the electrode is selectively mountable on and removable from the scope portion (paragraphs [11], [12] and [32]).

Regarding claim 8, Friedman'167 discloses that the sheath can also be permanently bonded to the probe (paragraphs [34] and [35]).

Regarding claims 12 and 13, Friedman'167 discloses the electrode having a length of 7-10mm along an axial direction of the probe and being separated from a second electrode by a distance of 5-8mm (Fig. 3).

Regarding claim 15, Friedman'167 discloses an electrode assembly that is one of a single use assembly and a multiple use assembly, in that a single use assembly is defined identically to a removable and selectively mountable assembly, and a multiple use assembly is synonymous with a permanently bonded assembly as discussed with regards to claim 6, 8 and 9.

Regarding claim 20, Friedman'167 discloses a method of treating a heart of a patient comprising the steps of inserting a flexible echocardiography probe into the patient's esophagus, performing an echocardiography to analyze the condition of the heart, and applying electric current to the at least one cardioversion electrode to supply a current to the heart (paragraphs [13]-[17]).

Regarding claim 21, Friedman'167 discloses performing an additional echocardiography immediately after the cardioversion using the echocardiography transducer (paragraph [18]).

Regarding claims 22 and 23, Friedman'167 discloses coupling the electrode sheath to the probe prior to inserting the device into the esophagus and disposing of the sheath after completing the procedure (paragraphs [6], [7], [10], [11], [12], [32] and [33]).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman'167.

Regarding claim 11, Friedman'167 discloses the invention substantially as claimed but does not expressly disclose that the electrode is formed of a titanium foil. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method as taught by Friedman'167 with a titanium foil electrode, since it is well known in the art that titanium is a good material for electrode construction due to its relatively low cost, durability, biocompatibility, and good electrical conduction properties.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

5 September 2006


George Manuel
Primary Examiner